

**Appendix A (Summary of Safety And Effectiveness)****Submitter:**

John Gagliardi, President (contact person)  
 MidWest Process Innovation, LLC  
 7736 Woodside Court  
 Maineville, OH 45039  
 513-573-0085 (Telephone and fax) or  
 513-573-0519 (Telephone and fax)  
 JGAGL777@One.Net

**Trade Name:** The ATI 014FC Insulation and Continuity Tester

**Common Name:** Insulation Tester

**Classification Name:** Insulation Tester (21 CFR, Part 884.4160, 85HFG)

**Summary of Safety and Effectiveness:**

The ATI 014FC Insulation and Continuity Tester and InsulScan Insulation Testing System have the same indications for use, basic design, both are battery operated battery operated and rechargeable.

<u>Device/Predicate</u>	<u>Jac-Cell Medic ATI-014</u>	<u>InsulScan Insulation Testing System</u>
Indications for Use	Insulation / Continuity Testing	Insulation / Continuity Testing
Design	Tester and Accessories	Tester and Accessories
Materials	Aluminum Casing	Aluminum Casing
Performance	Voltage Insulation Tester	Voltage Insulation Tester
Sterility	N/A	N/A
Usage	Pre-operating Room	Pre-operating Room
Biocompatibility*	Not Required, Non-Patient Contact	Not Required, Non-Patient Contact
Target Population	Pre-operation nurses in Hospitals	Pre-operation nurses in Hospitals
Mechanical Safety	Accessory to a device	Accessory to a device

Revised to read: **Indications for Use:** The ATI-014 Insulation and Continuity Testing system is a non-destructive, non-patient contacting, voltage insulation tester designed to test the insulation of electrosurgical instruments.

9/29/02



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 03 2002

Jac-Cell Medic Corporation  
c/o Mr. John Gagliardi  
MidWest Process Innovation, LLC  
7736 Woodside Court  
Maineville, OH 45039

Re: K020334

Trade/Device Name: Insulation and Continuity Testing System  
Regulation Number: 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: August 12, 2002  
Received: August 15, 2002

Dear Mr. Gagliardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

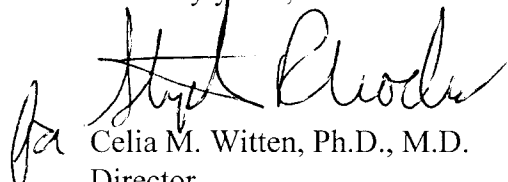
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K020334

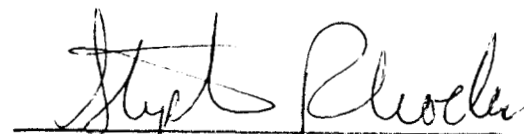
Device Name: INSULATION & CONTINUITY TESTING SYSTEM

**Indications for Use:**

The ATI-014 Insulation and Continuity Testing system is a non-destructive, non-patient contacting, voltage insulation tester designed to test the insulation of electrosurgical instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K020334